HOW TO DECIDE EXPEDITED VS EXEMPT STUDIES

Placement of a study in either the expedited or exempt research categories is often a judgment call rather than a hard line regulatory decision. These decisions become clearer with experience and dialogue with others.

This section has been designed to help investigators reflect on the distinction between expedited and exempt studies. The "How I decide whether a project is expedited or exempt" is an example of a possible thought process the IRB might use when reviewing a study. The side by side chart gives a general comparison of expedited and exempt studies.

HOW I DECIDE WHETHER A PROJECT IS EXPEDITED OR EXEMPT …PERSPECTIVE OF AN IRB REVIEWER

First, I look at the abstract and methodology and determine if it meets the federal definition of both human subject and research. If it does not meet both, then it becomes Not Human Subjects Research (NHSR) and a letter to that effect is provided.

If the project meets the definitions, and it is using data or specimens that are "coded" with no link available to the investigator, then these projects are also NHSR according to DHHS "Coded Specimen Guidance." A letter to that effect is provided.

For projects that still are not eliminated, I look at the six exemption categories and reflect on which category this project fits. Once I find an exemption category that this project seems to fit, I then check to see if the subjects are vulnerable subjects, children, if the investigator is keeping and collecting identifiers, if the information being gathered is of private or sensitive nature, and if there is a risk to participants from the information being collected? If the answers to any of these questions are "yes", then the project should <u>not</u> be exempt.

In comparing expedited and exempt projects, exempt are more of a "ho-hum" nature that <u>do not</u> collect identifiers, while expedited are more of an "uh-oh" and <u>do</u> collect identifiers. If the project does not appear to fit any exempt category, or there are yes answers to the questions posed, I forward the project as expedited or full board for further determination by IRB staff.

SIDE BY SIDE GUIDE TO DETERMINE EXPEDITED VS EXEMPT REVIEW CATEGORIES

Side by Side Guide to Determine Expedited vs Exempt Review Categories

(note: these are general guidelines, there may be exceptions)

Points to Consider	Expedited	Exempt
Is it Human Subjects Research?		
Involves Human Subjects	**X**	**X**
must meet federal definition of human subject		
It is Research	**X**	**X**
must meet federal definition of research		
Research Categories		
Project meets one or more of the expedited research categories	**X**	
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm		
Project meets one or more of the exempt research categories		**X**
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm		
Number of Interactions / Interventions with Subject		
Interactions once (e.g. one time anonymous survey)		**X**
no retention of personal / contact information		
Interaction more than once (i.e. design requires repeated interactions)	**X**	
Retains personal / contact information for additional interaction or follow-up		
Analyzing Data only (no interaction with human subjects)		
Anonymous data / de-identified / no identifiers maintained		**X**
may qualify as "Not Human Subjects Research" or Coded Specimen Research		
Data linked to personal information	**X**	
Level of risk		
Minimal	**X**	
risks not greater than those encountered in daily life, or routine physical / psychological exams / tests		
(e.g. interviews about levels of anxiety or depression, surveying children, blood draws)		
None or less than minimal		**X**
risk that is less than minimal as defined above (e.g. questionnaire asks for favorite food,		
# of vacations in past year, etc).		
Annual IRB Review (continuing review)		
Continuing Review is Required	**X**	
Continuing Review is NOT required		**X**

Points to Consider	Expedited	Exempt
Are the data (questions) collected (asked) sensitive in nature, or identifiable private information?		
Sensitive	**X**	
data could put the subject at risk (e.g. job loss, marriage, reputation, etc)		
Not sensitive		**X**
includes innocuous data/questions only (e.g. food preferences, cell phone usage)		
Identifiable Private Information	**X**	**X**
includes information about behavior occurring in a private context, information gathered for specific		
purposes where the individual expects the information to be kept private (e.g. medical records), and		
data/info is identifiable (e.g. name/address). NOTE: identifiable information can qualify as exempt if		
the information is innocuous.		
Intent or use of information gathered		
Generalizeable	**X**	**X**
intend to share information to benefit society		
Not intended to contribute to generalizeable knowledge	**NA**	**NA**
submit a "Human Subjects Research Determination Request"		
Who are the subjects?		
Children	**X**	***X**
*Exempt category 2 is allowable in studies with children, only when there is passive observation		
and no interaction with the children. Exempt categories 1 and 3 - 6 (45CFR46) can apply to research		
with children or adults.		
Pregnant Women (45CFR46 Subpart B)	**X**	**X**
Exempt research is allowable with pregnant women		
Expedited research with pregnant women requires extra considerations (45CFR46.204)		
Prisoners	**X**	
research with prisoners can not be exempt (45CFR46 Subpart A)		
Normals	**X**	**X**
generally healthy adults without physical / mental impairments		
Consent and Waivers of Consent		
Informed Consent	**X**	
includes all required elements of informed consent, signature required		
Waiver of Consent, if applicable	**X**	
request to waive entire consent process in some cases (i.e. no consent / no signature required)		
Waiver of Written Consent, if applicable	**X**	
request to waive signature requirement in some cases (i.e. consent without signature)		
Information Sheet (alternative / shortened consent)	**X**	**X**
"alternative" consent (i.e. contains some elements of informed consent, no signature obtained)		
NOTE: Information sheets usually apply to exempt research, but may be used in expedited research with an appropriate waiver of consent.		

Points to Consider	Expedited	Exempt
Who Can Approve the Study for the IRB?		
IRB Designee	**X**	**X**
includes IRB Chair, Vice Chair, Director, or designated members		
IRB Liaison or IRB Staff		**X**
school / department representatives (liaisons) or the IRB staff		
Research Methods		
Focus groups / Interviews	**X**	**X**
anonymity generally allows expedited or exempt		
Voice / Video / Photograph / Recordings	**X**	**X**
Involves Deception	**X**	**X**
Uses HIPAA identifiers	**X**	